

TRANSMITTAL OF APPEAL BRIEF (Small Entity)

Docket No.
A-8730

In Re Application Of: Nyle ELLIOTT et al.



Application No.	Filing Date	Examiner	Customer No.	Group Art Unit	Confirmation No.
10/720,213	November 25, 2003	Manuel A. Mendez	20741	3763	4978

Invention: SINGLE USE CATHETER

COMMISSIONER FOR PATENTS:

Transmitted herewith is the Appeal Brief in this application, with respect to the Notice of Appeal filed on:

May 26, 2006

Applicant claims small entity status. See 37 CFR 1.27

The fee for filing this Appeal Brief is: \$250.00

A check in the amount of the fee is enclosed.

The Director has already been authorized to charge fees in this application to a Deposit Account.

The Director is hereby authorized to charge any fees which may be required, or credit any overpayment to Deposit Account No. 08-2455. I have enclosed a duplicate copy of this sheet.

Payment by credit card. Form PTO-2038 is attached.

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

Signature

Dated: May 26, 2006

Christopher J. McDonald

Reg. No. 41,533

HOFFMAN, WASSON & GITLER, P.C.
2461 South Clark Street, Suite 522
Arlington, VA 22202
(703) 415-0100

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)] on _____.

(Date)

Signature of Person Mailing Correspondence

Typed or Printed Name of Person Mailing Correspondence

cc:



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of:

Nyle ELLIOTT et al.

Group Art Unit: **3763**

Serial No: **10/720,213**

Examiner: **Manuel A. Mendez**

Filed : **November 25, 2003**

For : **SINGLE USE CATHETER**

APPLICANT'S APPEAL BRIEF
UNDER 35 U.S.C. §41.37

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

(1) REAL PARTY IN INTEREST

The real party in interest is Oakington Corporation, the assignee of the application.

(2) RELATED APPEALS AND INTERFERENCES

There are no related appeals and interferences.

(3) STATUS OF CLAIMS

05/30/2006 JADD01 00000026 10720213

Claim 1-4, 7 and 8 are pending and stand rejected. The rejection of these claims is appealed.

(4) STATUS OF AMENDMENTS

A Request for Reconsideration was filed on April 25, 2006. An Advisory Action was mailed on May 12, 2006 but did not address the arguments presented by applicant.

(5) SUMMARY OF CLAIMED SUBJECT MATTER

The catheter has a balloon 26 inflated through a lumen 22. A one-way valve 32 in the inflation lumen allows inflation of the balloon, but prevents deflation. As explained in the second to last sentence on page 4 of the specification, the lumen must be cut in order to deflate the balloon. This ensures that the catheter may only be used once, which is a critical feature for hygienic reasons.

(6) GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Claims 1-4, 7 and 8 rejected as obvious over US 4,547,187 (Kelly) in view of US 6,811,559 (Thorton), US 6,682,508 (Meythaler et al.), US 5,293,875 (Stone) and US 3860007 (Binard et al.).

(7) ARGUMENT

Kelly discloses a catheter having a balloon 30 which is inflated through a port having a valve 20 best seen in Figures 6 and 7. This valve is not a one-way valve as it allows inflation and deflation of the balloon as explicitly stated in column 4, lines 37-38, which states "The valve 20 can be inflated and deflated directly with a hypodermic syringe 40" The patent also discloses a valve 52 which operates in the same manner, but uses a standard Luer tip syringe without a needle. As stated in column 5, lines 43-45, when discussing valve 52, "When the balloon

is to be deflated, the tip is again inserted until it opens the slit whereupon the air is released into the syringe."

Kelly does not disclose the one-way port disclosed and claimed in the application and Binard does not cure this deficiency. Binard discloses a catheter with a safety deflation means where the balloon *may* be deflated through the deflation movement by severing the catheter shaft adjacent its proximal end when the inflation movement is obstructed. But Binard et al. does not disclose a one-way port allowing inflation but preventing deflation through the port. Column 2, lines 39-42 discloses "... an inflation lumen extending between the inside of the balloon and adjacent the proximal end of the shaft, and valve means for controlling inflation and deflation of the balloon." Both Kelly and Binard et al. disclose two-way valves, allowing both inflation and deflation of the balloon and therefore no prior art, taken alone or in combination, discloses or suggests the limitations in claims 1 and 7 regarding a one-way port preventing deflation of the balloon and necessitating cutting of the catheter for removal and ensuring its single use and avoiding reuse contamination.

The distinction between a catheter with a two way valve, such as Kelly and Binard et al., and a one way valve, as the invention, is a direct result of their respective functions. The catheters disclosed by both Kelly, a cholangiography inserted in a bile duct, and Binard, a urinary drainage catheter, are designed to be reused. The catheter of the invention, a rectal catheter, cannot be adequately sterilized to be used more than once. The one way valve requires the catheter be cut for removal and makes it impossible to be reused. The use of the catheter dictates the use of a one way valve to guarantee the single use of the catheter to preserve medical hygiene. Such concerns are not present in the prior art cited by the Examiner and explain their use of a two one

valve. The two way valve allows deflation of the balloon without destroying the catheter, enabling their reuse. The deflation of the balloon through the valve is explicitly disclosed by both Kelly and Binard.

The remaining patents are cited for features separate from the one way valve and do not cure the deficiencies noted above.

It is respectfully requested that the rejections be overturned and the application allowed to issue.

Respectfully submitted,



Christopher J. McDonald
Reg. No. 41,533

May 22, 2006

HOFFMAN, WASSON & GITLER, PC
2461 South Clark Street
Suite 522
Arlington, VA 22202
(703) 415-0100

CLAIMS APPENDIX

1. A single use catheter, comprising:
 - a lumen having a proximate end and a distal end,
 - an inflatable cuff surrounding said lumen,
 - said lumen having a first and second conduit,
 - said first conduit in fluid communication with said inflatable cuff,
 - said second conduit in fluid communication with said proximate end of said lumen,
 - a port at an end of said first conduit, and
 - a one-way valve in said port, said one-way port allowing inflation of said cuff but not allowing deflation whereby said first conduit must be cut to deflate said cuff.
2. The single use catheter of claim 1, further comprising a syringe attached to said port.
3. The single use syringe of claim 1, further comprising a hydrophobic filter tip on said lumen proximate end.
4. The single use syringe of claim 1, further comprising a charcoal filter in said second conduit.

7. A single use catheter, comprising:
 - a first conduit having a proximate end and a distal end,
 - a second conduit having a proximate end and a distal end, said second conduit parallel to said first conduit,

an inflatable cuff surrounding said first and second conduits,

 said first conduit in fluid communication with said inflatable cuff, and

 a one way valve at said distal end of said first conduit, said one-way port allowing inflation of said cuff but not allowing deflation whereby said first conduit must be cut to deflate said cuff.

8. The single use syringe of claim 7, further comprising:

 a port at said first conduit distal end, and

 a syringe attached to said port.

EVIDENCE APPENDIX

None

RELATED PROCEEDINGS APPENDIX

None